

Subject: RE: waived test rule

Date: Sun, 13 Aug 2000 10:42:43 -0400

From: "Sliva, Clara A." <CAS@CDRH.FDA.GOV>

To: "Duwe" <duwe@value.net>

2949 '00 AUG 22 A9:58

Thank you for your interest.
CLIA regulates tests by complexity.

Also, Please send your written comments to the following address

REFERENCE Docket No. 00N-1394
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857

> -----Original Message-----

> From: Duwe [SMTP:duwe@value.net]

> Sent: Friday, August 11, 2000 11:24 PM

> To: CAS@CDRH.FDA.GOV

> Subject: Re: waived test rule

>

> Dear Ms. Sliva,

> Since I cannot attend your meeting in Washington, DC, on the 14th and
> 15th, I would like to send my comments via e-mail. As a consumer who
> would like to have direct access to salivary testing for my hormone
> evaluation I would like to urge the Secretary to confer "Waived status" to
> saliva testing. I know that saliva collection is as easy as it is
> non-invasive. Also, it is much cheaper than blood testing and, from what
> I have read, just as accurate as blood if not more so.

>

> According to my understanding of FDA guidelines, a test can receive waived
> status if it is a simple laboratory procedure that "the Secretary has
> determined pose[s] no unreasonable risk of harm to the patient if
> performed incorrectly". Saliva hormone collection materials should be
> available in drug stores so that I can send my saliva sample to a
> qualified laboratory without the necessity of having a healthcare provider
> sign for it. This signature requirement adds unnecessary expense to the
> procedure. Any erroneous result would not pose a significant risk of harm
> since these saliva hormones are tested more than once in order to evaluate
> changing baseline levels of the estrogens, progesterone, testosterone,
> DHEA, cortisol and melatonin. Thus, the tests would have to be in error
> repeatedly - highly unlikely. In addition, saliva testing is also
> extremely useful in monitoring levels of hormone supplementation - making
> sure that the dose is high enough to receive the benefits of the hormone
> but not more than is needed. Because these hormone levels fluctuate
> naturally, an incorrect result here would be far less damaging than a
> false negative fecal occult blood test or a false negative pregnancy test.
> These two aforementioned tests have waived status.

>

> I feel that, with the aid of a Result Interpretation Guide that
> accompanies saliva test results, I can successfully evaluate my hormone
> levels. I really do not need a doctor to do this. These results give me
> valuable information that I can bring to my doctor if I think that I need
> hormone supplementation (which requires a prescription). Then my doctor
> and I can enter into an informed dialog as to my hormonal needs and
> solutions.

>

> Thank you very much for your attention.

Gail Duwe

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Reference Docket No. CON - 1394
Dockets Management Branch (HFA-305)
Food and Drug Administration
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